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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/439,311 11/12/99 LEE L 78.560

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DEPARTMENT OF THE NAVY
NAVAL MEDICAL RESEARCH CENTER
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EXAMINER

PORTNER, V

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 03/01/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/439,311

Applicant(s)
Lee et al

Examiner
Portner

Group Art Unit
1645

☒ Responsive to communication(s) filed on Nov 12, 1999

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-15 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-15 are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 1-15 are pending.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1,4-7, drawn to nucleic acid, vector, expression system, classified in class 514, subclass 44.
 - II. Claim 2, drawn to polypeptide, classified in class 530, subclass 350.
 - III. Claims 8-15, drawn to various methods of inducing an immune response, classified in class 424, subclass 234.1 .
2. The inventions are distinct, each from the other because of the following reasons:
3. The invention of group I is distinct from the invention of group II because it is drawn to materially different compositions that require non-coextensive areas of search and consideration. For example, the polypeptides of the invention of Group II may be isolated from natural sources and are not necessarily defined by the DNAs that encode them.
4. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different

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process of using that product , specifically in methods of detecting antibodies, in methods of purifying antibodies, as well as in methods of generating a vaccine .

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

1. Claim 8, 10,11,12,13 contains at least FlaA Campylobacter polypeptide;
2. Claim 14 utilizes a conjugate of two proteins (one from E.coli,. the other FlaA of Campylobacter) with or without an additional adjuvant.
3. Claim 15 is a multivalent vaccine conjugate together with a specific LT adjuvant (two antigens (MBP and LT) from E.coli, and FlaA from Campylobacter);
4. Claim 9 uses known multivalent vaccine formulations together with at least FlaA from Campylobacter.

6. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

7. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon,

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including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

8. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification, recognized divergent subject

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matter, and because the searches required for the separate groups of inventions are non-coextensive, restriction for examination purposes as indicated is proper.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Drawings

13. This application has been filed with drawings which are acceptable for examination purposes. See attached PTO-948.

Sequence Compliance

14. It was noted that specific sequences are shown in Figure 3 that have not been assigned SEQ ID Nos. These sequences should be assigned SEQ ID NOS and either the Brief Description of the Drawings or Figure 3 should be amended to include these numbers to place the Application in Sequence compliance.

If the sequences shown in Figure 3 have not been submitted in the attached Sequence Listing pages, then they should be added and new pages submitted.

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If these sequences have not previously been submitted in Computer Readable form, a new Sequence Disk should be submitted that contains these sequences as well.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

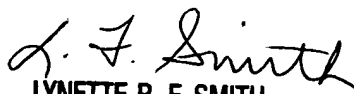
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

February 27, 2001


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600